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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/975,139      | 10/10/2001  | Volker Schellenberger | 23623-7060          | 8883             |

7590 12/15/2003

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EXAMINER

MAHATAN, CHANNING

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                       |  |
|------------------------------|------------------------|-----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>   |  |
|                              | 09/975,139             | SCHELLENBERGER ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>       |  |
|                              | Channing S Mahatan     | 1631                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 11, 14-29, and 31 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 14-29 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-7, 11, 14-29 and 31 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3 Sheets</u> | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *APPLICANTS' ELECTION*

Applicants' election with traverse of Group I (claims 1-6, 11, 14-29, and 31; directed to methods and systems for creating libraries of nucleic acid sequences) is acknowledged.

Applicants traversal argument is that claim 7 (Group II) should be joined with Group I on the grounds that Claim 7 is dependent upon Claim 1 and there is no undue search burden to search the additional claim/group. *This is not persuasive. Burden of search has been established.*

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-6, 11, 14-29, and 31. Claim 7 is withdrawn as not directed to the elected invention. Claims 8-10, 12, 13, and 30 have been cancelled.

## Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### *NON-STATUTORY SUBJECT MATTER*

Claim 11 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter as necessitated by amendment. The preamble of claim 11 indicates "A system for creating libraries of nucleic acid sequences that encode variants of protein" and the body of the claim further indicates: a) nucleic acid sequence, b) probability matrix, and c) constraint vector. Applicants' state the following in the specification:

"A probability matrix is generated to provide an estimate that a given residue will provide a desired activity in a biological polymer of interest." (page 15, lines 9-10)

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“The constraint vector preferably should reflect the likelihood that a specific mutation at each amino acid position of a protein will improve or affect the desired function of that protein.” (page 17, lines 25-27)

In view of the specification and absence of physical elements (i.e. device), the nucleic acid sequence, probability matrix, and constraint vector are interpreted to reflect merely data (i.e. letters and numbers).

M.P.E.P. section entitled “Nonfunctional Descriptive Material” (pages 2100-13, right column) states:

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such “descriptive material” is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

Thus, the nucleic sequence, probability matrix, and constraint vector is descriptive material (i.e. data) which fails to exhibit any function interrelationship with, for example, a computer.

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Further, it should be noted the preamble of the claim recites a system with the intention of creating libraries, however, absent are any physical devices, particularly a physical device to create libraries.

**Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 11, 14-29, and 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claim 11 recites in the preamble “A system for creating libraries of nucleic acid sequences that encode variants of a protein”, however, absent from the body of the claim are any physical devices which is confusing as the claim is directed to an apparatus. Clarification of the metes and bounds, via clearer claim language is requested.

Claims 23 and 25 recite the limitation “the probability matrix is an algorithm”/“the constraint vector is an algorithm” which is confusing. Claim 1 (as written) and the specification (refer to cited definitions in the above 35 U.S.C. § 101 rejection) indicate the probability matrix and constraint vector are data representations and not algorithms as recited in claims 23 and 25. It is unclear if Applicants intend the probability matrix and constraint vector of claim 1 be derived from an algorithm. Clarification of the metes and bounds, via clearer claim language, is requested.

### **Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 14-29, and 31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Marr et al. (U.S. Patent Number 5,701,256).

Marr et al. (U.S. Patent Number 5,701,256) discloses a method and apparatus for comparing biological sequences from a known source of sequences (Abstract). The apparatus takes as input a set of target similarity levels (such as evolutionary distances in units of PAM), and finds all fragments of known sequences that are similar to the subject sequence at each target similarity level, and are long enough to be statistically significant. The invention device filters out fragments from the known sequences that are too short, or have a lower average similarity to the subject sequence than is required by each target similarity level (i.e. constraint; Column 4, lines 42-46). The subject sequence is then compared only to the remaining known sequences to find the best matches. The filtering member divides the subject sequence into overlapping blocks, each block being sufficiently large to contain a minimum-length alignment from a known sequence. For each block, the filter member compares the block with every possible short fragment in the known sequences and determines a best match for each comparison. The determined set of short fragment best matches for the block provide an upper threshold on alignment values. Regions of a certain length from the known sequences that have a mean alignment value upper threshold greater than a target unit score are concatenated to form a union.

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The current block is compared to the union and provides an indication of best local alignment with the subject sequence. The information is then transferred to a DNA library for construction (Columns 12-14, beginning on line 63). Thus, Marr et al. anticipates the claimed invention.

It should be noted Applicants' provide the following with regard to probability matrix and constraint vector:

"The phrase "probability matrix" refers to a matrix for determining the probability that an amino acid can be substituted with another amino acid." (page 14, lines 17-18 of the Specification).

"The phrase "constraint vector" refers to a constraint put on or "applied to" the probability matrix to determine whether and the degree to which mutations at a given position in the matrix are to be included in the library." (page 15, lines 3-5 of the Specification)

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *December 11, 2003*

Examiner Initials: *CSM*

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800  
#41631